

60 DURABLE MEDICAL EQUIPMENT

60-3 WHITE CANE FOR USE BY A BLIND PERSON--NOT COVERED

A white cane for use by a blind person is more an identifying and self-help device than an item which makes a meaningful contribution in the treatment of an illness or injury.

60-4 HOME USE OF OXYGEN

A. General.--Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6) of the Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D. This section also includes **special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included in subsection F.**

B. Medical Documentation.--Initial claims for oxygen services must include a completed Form HCFA-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. **The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form HCFA-484 for recertifications. (See Medicare Carriers Manual §3312 for completion of Form HCFA-484.)**

The medical and prescription information in section B of Form HCFA-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by non-physician clinician or a physician employee, it must be reviewed and the form HCFA-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. (See Medicare Carriers Manual, Part 3, §4105.5.) This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:

- o A diagnosis of the disease requiring home use of oxygen;
- o The oxygen flow rate; and

o An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

NOTE: A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the carrier's medical staff should review all claims with oxygen flow rates of more than 4 liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed form HCFA-484. In addition the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the noncontinuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the carrier in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

Carriers are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in Medicare Carriers Manual, Part 3, §4105.5. When indicated, carriers may also request documentation of the results of a repeat arterial blood gas or oximetry study.

NOTE: Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See Medicare Carriers Manual §4105.5 for certification and retesting schedules.)

C. Laboratory Evidence.--Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO₂) in arterial blood. (See Medicare Carriers Manual, Part 3, §2070.1 for instructions on clinical laboratory tests.) A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending physician and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines. This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the carrier needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood

gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than 2 days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.”

Carriers may accept a attending physician’s statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the carrier has reason to believe that there has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

D. Health Conditions.--Coverage is available for patients with significant hypoxemia in the chronic stable state, i.e, not during a period of acute illness or an exacerbation of their underlying disease, if: (1) the attending physician has determined that the patient has a health condition outlined in subsection D.1, (2) the patient meets the blood gas evidence requirements specified in subsection D.3, and (3) the patient has appropriately tried other treatment without complete success. (See subsection B.)

1. Conditions for Which Oxygen Therapy May Be Covered.--

- o A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or
- o Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

2. Conditions for Which Oxygen Therapy Is Not Covered.--

- o Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments;
- o Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;
- o Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO₂ improves the oxygenation of tissues with impaired circulation; or
- o Terminal illnesses that do not affect the lungs.

3. Covered Blood Gas Values.--If the patient has a condition specified in subsection D.1, the carrier must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see subsections B and C) and determine if coverage is available under one of the three group categories outlined below.

a. Group I.--Except as modified in subsection d, coverage is provided for patients with significant hypoxemia evidenced by any of the following:

(1) An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken at rest, breathing room air.

(2) An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO₂ more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.

(3) An arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

b. Group II.--Except as modified in subsection d, coverage is available for patients whose arterial PO₂ is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent, if there is evidence of:

(1) Dependent edema suggesting congestive heart failure;

(2) Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or

(3) Erythrocythemia with a hematocrit greater than 56 percent.

c. Group III.--Except as modified in subsection d, carriers must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO₂ levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent. In order for claims in this category to be reimbursed, the carrier's reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims. HCFA expects few claims to be approved for coverage in this category.

d. Variable Factors That May Affect Blood Gas Values.--In reviewing the arterial PO₂ levels and the arterial oxygen saturation percentages specified in subsections D. 3. a, b and c, the carrier's medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

E. Portable Oxygen Systems.--A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself or (2) to use in addition to a stationary oxygen system. Portable oxygen is not covered when it is provided only as a backup to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- o The claim meets the requirements specified in subsections A-D, as appropriate; and
- o The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep

F. Respiratory Therapists.--Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B durable medical equipment benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

(See §60-9; Intermediary Manual, Part 3, §3113ff; and Medicare Carriers Manual, Part 3, §2100ff.)

60-5 POWER-OPERATED VEHICLES THAT MAY BE USED AS WHEELCHAIRS

Power-operated vehicles that may be appropriately used as wheelchairs are covered under the durable medical equipment provision.

These vehicles have been appropriately used in the home setting for vocational rehabilitation and to improve the ability of chronically disabled persons to cope with normal domestic, vocational and social activities. They may be covered if a wheelchair is medically necessary and the patient is unable to operate a wheelchair manually.

A specialist in physical medicine, orthopedic surgery, neurology, or rheumatology must provide an evaluation of the patient's medical and physical condition and a prescription for the vehicle to assure that the patient requires the vehicle and is capable of using it safely. When an intermediary determines that such a specialist is not reasonably accessible, e.g., more than 1 day's round trip from the beneficiary's home, or the patient's condition precludes such travel, a prescription from the beneficiary's physician is acceptable.

The intermediary's medical staff reviews all claims for a power-operated vehicle, including the specialists' or other physicians' prescriptions and evaluations of the patient's medical and physical conditions, to insure that all coverage requirements are met. (See §60-9 and Intermediary Manual, Part 3, §3629.)

60-6 SPECIALLY SIZED WHEELCHAIRS

Payment may be made for a specially sized wheelchair even though it is more expensive than a standard wheelchair. For example, a narrow wheelchair may be required because of the narrow doorways of a patient's home or because of a patient's slender build. Such difference in the size of the wheelchair from the standard model is not considered a deluxe feature.

A physician's certification or prescription that a special size is needed is not required where you can determine from the information in file or other sources that a specially sized wheelchair (rather than a standard one) is needed to accommodate the wheelchair to the place of use or the physical size of the patient.

To determine the reasonable charge in these cases, use the criteria set out in Carriers Manual, §§5022, 5022.1, 5200, and 5205, as necessary.

Cross-refer: Intermediary Manual, §§3113.2C, 3642.1, 3643 (item 3); Carriers Manual, §§2100.2c, 2105, 4105.2, 5107; Hospital Manual, §§235.2c, 420.1 (item 13).

60-7 SELF-CONTAINED PACEMAKER MONITORS

Self-contained pacemaker monitors are accepted devices for monitoring cardiac pacemakers. Accordingly, program payment may be made for the rental or purchase of either of the following pacemaker monitors when it is prescribed by a physician for a patient with a cardiac pacemaker:

A. Digital Electronic Pacemaker Monitor.--This device provides the patient with an instantaneous digital readout of his pacemaker pulse rate. Use of this device does not involve professional services until there has been a change of five pulses (or more) per minute above or below the initial rate of the pacemaker; when such change occurs, the patient contacts his physician.

B. Audible/Visible Signal Pacemaker Monitor.--This device produces an audible and visible signal which indicates the pacemaker rate. Use of this device does not involve professional services until a change occurs in these signals; at such time, the patient contacts his physician.

NOTE: The design of the self-contained pacemaker monitor makes it possible for the patient to monitor his pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider.

Therefore, documentation of the medical necessity for pacemaker evaluation in the outpatient department of the provider should be obtained where such evaluation is employed in addition to the self-contained pacemaker monitor used by the patient in his home.

Cross-refer: §50-1

60-8 SEAT LIFT

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.

Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance. Excluded from coverage is the type of lift which operates by a spring release mechanism with a sudden, catapult-like motion and jolts the patient from a seated to a standing position. Limit the payment for units which incorporate a recliner feature along with the seat lift to the amount payable for a seat lift without this feature.

Cross Refer: Carriers Manual, § 5107

60-9 DURABLE MEDICAL EQUIPMENT REFERENCE LIST.

The durable medical equipment (DME) list which follows is designed to facilitate your processing of DME claims. This section is designed to be used as a quick reference tool for determining the coverage status of certain pieces of DME and especially for those items which are commonly referred to by both brand and generic names. The information contained herein is applicable (where appropriate) to all DME coverage determinations discussed in the DME portion of this manual. The list is organized into two columns. The first column lists alphabetically various generic categories of equipment on which national coverage decisions have been made by HCFA; and the second column notes the coverage status of each equipment category.

In the case of equipment categories that have been determined by HCFA to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. With respect to equipment categories that cannot be covered as DME, the list includes a brief explanation of why the equipment is not covered. This DME list will be updated periodically to reflect any additional national coverage decisions that HCFA may make with regard to other categories of equipment.

When you receive a claim for an item of equipment which does not appear to fall logically into any of the generic categories listed, you have the authority and responsibility for deciding whether those items are covered under the DME benefit. These decisions must be made by each contractor based on the advice of its medical consultants, taking into account:

- o The general DME coverage instructions in the Carriers Manual, §2100ff and Intermediary Manual, §3113ff (see below for brief summary);
- o Whether the item has been approved for marketing by the Food and Drug Administration (FDA) (see Carriers Manual, §2303.1 and Intermediary Manual, §3151.1) and is otherwise generally considered to be safe and effective for the purpose intended; and
- o Whether the item is reasonable and necessary for the individual patient.

As provided in the Carriers Manual, § 2100.1, and Intermediary Manual, §3113.1, the term DME is defined as equipment which

- o Can withstand repeated use; i.e., could normally be rented, and used by successive patients;
- o Is primarily and customarily used to serve a medical purpose;
- o Generally is not useful to a person in the absence of illness or injury; and
- o Is appropriate for use in a patient's home.

Durable Medical Equipment Reference List:

<u>Item</u>	<u>Coverage Status</u>
Air Cleaners	--deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act)
Air Conditioners	--deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act)
Air-Fluidized Bed	--(See §60-19.)
Alternating Pressure Pads, and Mattresses and Lambs Wool Pads	--covered if patient has, or is highly susceptible to, decubitus ulcers and patient's physician has specified that he will be supervising its use in connection with his course of treatment.
Audible/Visible Signal Pacemaker Monitor	--(See Self-Contained Pacemaker Monitor.)
Augmentative Communication Device	--(See Speech Generating Devices, §60-23.)
Bathtub Lifts	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Bathtub Seats	--deny--comfort or convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act)
Bead Bed -	--(See §60-19.)
Bed Baths (home type)	--deny--hygienic equipment; not primarily medical in nature (§1861(n) of the Act)
Bed Lifter (bed elevator)	--deny--not primarily medical in nature (§1861(n) of the Act.

Bedboards	--deny--not primarily medical in nature (§1861(n) of the Act)
Bed Pans (autoclavable hospital type)	--covered if patient is bed confined
Bed Side Rails	--(See Hospital Beds, §60-18.)
Beds-Lounge (power or manual)	--deny--not a hospital bed; comfort or convenience item; not primarily medical in nature (§1861(n) of the Act)
Beds--Oscillating	--deny--institutional equipment; inappropriate for home use
Bidet Toilet Seat	--(See Toilet Seats.)
Blood Glucose Analyzer-- Reflectance Colorimeter	--deny--unsuitable for home use (See §60-11.)
Blood Glucose Monitor	--covered if patient meets certain conditions (See §60-11.)
Braille Teaching Texts	--deny--educational equipment; not primarily medical in nature (§1861(n) of the Act)
Canes	--covered if patient's condition impairs ambulation (See §60-3.)
Carafes	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Catheters	--deny--nonreusable disposable supply (§1861(n) of the Act)
Commodes	--covered if patient is confined to bed or room

NOTE: The term "room confined" means that the patient's condition is such that leaving the room is medically contraindicated. The accessibility of bathroom facilities generally

would not be a factor in this determination. However, confinement of a patient to his home in a case where there are no toilet facilities in the home may be equated to room confinement. Moreover, payment may also be made if a patient's medical condition confines him to a floor of his home and there is no bathroom located on that floor (See hospital beds in §60-18 for definition of "bed confinement".)

| Communicator

--(See §60-23, Speech Generating Devices)

Continuous Passive Motion

--Continuous passive motion devices are devices covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the three week period following surgery during which the device is used in the patient's home.

There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.

Continuous Positive Airway Pressure (CPAP)

--(See §60-17.)

Crutches

--covered if patient's condition impairs Ambulation

Cushion Lift Power Seat

--(See Seat Lifts.)

Dehumidifiers (room or central heating system type)

--deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act

Diathermy Machines (standard pulses wave types)	--deny--inappropriate for home use (See and §35-41.)
Digital Electronic Pacemaker Monitor	--(See Self-Contained Pacemaker Monitor.)
Disposable Sheets and Bags	--deny--nonreusable disposable supplies (§1861(n) of the Act)
Elastic Stockings	--deny--nonreusable supply; not rental-type items (§1861(n) of the Act)
Electric Air Cleaners	--deny--(See Air Cleaners.) (§1861(n) of the Act)
Electric Hospital Beds	--(See Hospital Beds §60-18.)
Electrostatic Machines	--deny--(See Air Cleaners and Air Conditioners.) (§1861(n) of the Act)
Elevators	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Emesis Basins	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Esophageal Dilator	--deny--physician instrument; inappropriate for patient use
Exercise Equipment	--deny--not primarily medical in nature (§1861(n) of the Act)
Fabric Supports	--deny--nonreusable supplies; not rental-type it (§1861(n) of the Act)
Face Masks (oxygen)	--covered if oxygen is covered (See § 60-4.)
Face Masks (surgical)	--deny--nonreusable disposable items (§1861(n) of the Act)

Flowmeter	--(See Medical Oxygen Regulators.)
Fluidic Breathing Assister	--(See IPPB Machines.)
Fomentation Device	--(See Heating Pads.)
Gel Flotation Pads and Mattresses	--(See Alternating Pressure Pads and Mattresses.)
Grab Bars	--deny--self-help device; not primarily medical in nature (§1861(n) of the Act)
Heat and Massage Foam Cushion Pad	--deny--not primarily medical in nature; personal comfort item (§§1861(n) and 1862(a)(6) of the Act)
Heating and Cooling Plants	--deny--environmental control equipment not primary; medical in nature (§1861(n) of the Act)
Heating Pads	--covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heating pad is therapeutically effective.
Heat Lamps	--covered if the contractor's medical staff determines patient's medical condition is one for which the application of heat in the form of a heat lamp is therapeutically effective.
Hospital Beds	--(See §60-18.)
Hot Packs	--(See Heating Pads.)
Humidifiers (oxygen)	--(See Oxygen Humidifiers.)
Humidifiers (room or central heating system types)	--deny--environmental control equipment; not medical in nature (§1861(n) of the Act)
Hydraulic Lift	--(See Patient Lifts.)

Incontinent Pads	--deny--nonreusable supply; hygienic item (§ 1861(n) of the Act.)
Infusion Pumps	--For external and implantable pumps, see §60-14. If the pump is used with an enteral or parenteral nutritional therapy system, see §§65-10 - 65.10.2 for special coverage rules.
Injectors (hypodermic jet	--deny--noncovered self-administered drug supply;pressure powered devices (§1861(s)(2)(A) of the Act) for injection of insulin)
IPPB Machines	--covered if patient's ability to breathe is severely impaired
Iron Lungs	--(See Ventilators.)
Irrigating Kit	--deny--nonreusable supply; hygienic equipment (§1861(n) of the Act)
Lambs Wool Pads	--covered under same conditions as alternating pressure pads and mattresses
Leotards	--deny--(See Pressure Leotards.) (§1861(n) of the Act)
Lymphedema Pumps	--covered (See §60-16.) (segmental and non-segmental therapy types)
Massage Devices	--deny--personal comfort items; not primarily medical in nature (§§1861(n) and 1862(a)(6) of the Act)
Mattress	--covered only where hospital bed is medically necessary (Separate Charge for replacement mattress should not be allowed where hospital bed with mattress is rented.) (See §60-18.)

Medical Oxygen Regulators	--covered if patient's ability to breathe is severely impaired (See §60-4.)
Mobile Geriatric Chair	--(See Rolling Chairs.)
Motorized Wheelchairs	--(See Wheelchairs (power operated).)
Muscle Stimulators	--Covered for certain conditions (See §35-77.)
Nebulizers	--covered if patient's ability to breathe is severely impaired
Oscillating Beds	--deny--institutional equipment--inappropriate for home use
Overbed Tables	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Oxygen	--covered if the oxygen has been prescribed for use in connection with medically necessary durable medical equipment (See §60-4.)
Oxygen Humidifiers	--covered if a medical humidifier has been prescribed for use in connection with medically necessary durable medical equipment for purposes of moisturizing oxygen (See §60-4.)
Oxygen Regulators (Medical)	--(See Medical Oxygen Regulators.)
Oxygen Tents	--(See § 60-4.)
Paraffin Bath Units (Portable)	--(See Portable Paraffin Bath Units.)
Paraffin Bath Units (Standard)	--deny--institutional equipment; in appropriate or home use
Parallel Bars	--deny--support exercise equipment; primarily for institutional use; in the home setting other devices (e.g., a walker) satisfy the patient's need

Patient Lifts	--covered if contractor's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest or retard deterioration in his condition.
Percussors	--covered for mobilizing respiratory tract secretions in patients with chronic obstructive lung disease, chronic bronchitis, or emphysema, when patient or operator of powered percussor has received appropriate training by a physician or therapist, and no one competent to administer manual therapy is available.
Portable Oxygen Systems:	
1. Regulated (adjustable covered under conditions specified in flow rate) §60-4. Refer all claims to medical staff for this determination.	
2. Preset (flow rate deny emergency, first-aid, or not adjustable) precautionary equipment; essentially not therapeutic in nature.	
Portable Paraffin Bath Units	--covered when the patient has undergone a successful trial period of paraffin therapy ordered by a physician and the patient's condition is expected to be relieved by long term use of this modality.
Portable Room Heaters	--deny--environmental control equipment; not primarily medical in nature (§1861(n) of the Act)
Portable Whirlpool Pumps	--deny--not primarily medical in nature; personal comfort items (§§1861(n) and 1862(a)(6) of the Act)
Postural Drainage Boards	--covered if patient has a chronic pulmonary condition
Preset Portable Oxygen Units	--deny--emergency, first-aid, or precautionary equipment; essentially not therapeutic in nature

Pressure Leotards	--deny--non-reusable supply, not rental-type item (§1861(n) of the Act)
Pulse Tachometer	--deny--not reasonable or necessary for monitoring pulse of homebound patient with or without a cardiac pacemaker
Quad-Canes	--(See Walkers.)
Raised Toilet Seats	--deny--convenience item; hygienic equipment; not primarily medical in nature (§1861(n) of the Act)
Reflectance Colorimeters	--(See Blood Glucose Analyzers.)
Respirators	--(See Ventilators.)
Rolling Chairs	<p>--covered if the contractor's medical staff determines that the patient's condition is such that there is a medical need for this item and it has been prescribed by the patient's physician in lieu of a wheelchair. Coverage is limited to those roll-about chairs having casters of at least 5 inches in diameter and specifically designed to meet the needs of ill, injured, or otherwise impaired individuals.</p> <p>Coverage is denied for the wide range of chairs with smaller casters as are found in general use in homes, offices, and institutions for many purposes not related to the care or treatment of ill or injured persons. This type is not primarily medical in nature. (§1861(n) of the Act)</p>
Safety Roller	--(See §60-15.)
Sauna Baths	--deny--not primarily medical in nature; personal comfort items (§§1861(n) and (1862(a)(6) of the Act)

Seat Lift	--covered under the conditions specified in §60-8 Refer all to medical staff for this determination.
Self Contained Pacemaker Monitor	--covered when prescribed by a physician for a patient with a cardiac pacemaker (See §§50-1C and 60-7.)
Sitz Bath	--covered if the contractor's medical staff determines patient has an infection or injury of the perineal area and the item has been prescribed by the patient's physician as a part of his planned regimen of treatment in the patient's home.
Spare Tanks of Oxygen	--deny--convenience or precautionary supply
Speech Teaching Machine	--deny--education equipment; not primarily medical in nature (§1861(n) of the Act)
Stairway Elevators	--deny--(See Elevators.) (§1861(n) of the Act)
Standing Table	--deny--convenience item; not primarily medical in nature (§1861(n) of the Act)
Steam Packs	--these packs are covered under the same condition as a heating pad (See Heating Pads.)
Suction Machine	--covered if the contractor's medical staff determines that the machine specified in the claim is medically required and appropriate for home use without technical or professional supervision.
Support Hose	--deny (See Fabric Supports.) (§1861(n) of the Act)
Surgical Leggings	--deny--non-reusable supply; not rental-type item (§1861(n) of the Act)
Telephone Alert Systems	--deny--these are emergency communications systems and do not serve a diagnostic or therapeutic purpose

Telephone Arms	--deny--convenience item; not medical in nature (§1861(n) of the Act)
Toilet Seats	--deny--not medical equipment (§1861(n) of the Act)
Traction Equipment	--covered if patient has orthopedic impairment requiring traction equipment which prevents ambulation during the period of use (Consider covering devices usable during ambulation; e.g., cervical traction collar, under the brace provision)
Trapeze Bars	--covered if patient is bed confined and the patient needs a trapeze bar to sit up because of respiratory condition, to change body position for other medical reasons, or to get in and out of bed.
Treadmill Exerciser	--deny--exercise equipment; not primarily medical in nature (§1861(n) of the Act)
Ultraviolet Cabinet	--covered for selected patients with generalized intractable psoriasis. Using appropriate consultation, the contractor should determine whether medical and other factors justify treatment at home rather than at alternative sites, e.g., outpatient department of a hospital.
Urinals autoclavable	--covered if patient is bed confined hospital type
Vaporizers	--covered if patient has a respiratory illness
Ventilators	--covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive and negative pressure types.

Walkers	--covered if patient's condition impairs ambulation (See also §60-15.)
Water and Pressure Pads and Mattresses	--(See Alternating Pressure Pads and Mattresses.)
Wheelchairs	--covered if patient's condition is such that without the use of a wheelchair he would otherwise be bed or chair confined. An individual may qualify for a wheelchair and still be considered bed confined.
Wheelchairs (power operated)	--covered if patient's condition is such and wheelchairs with other that a wheelchair is medically necessary special features and the patient is unable to operate the wheelchair manually. Any claim involving a power wheelchair or a wheelchair with other special features should be referred for medical consultation since payment for the special features is limited to those which are medically required because of the patient's condition. (See §60-5 for power operated and §60-6 for specially sized wheelchairs.) <u>NOTE:</u> A power-operated vehicle that may appropriately be used as a wheelchair can be covered. (See §60-5 for coverage details.)
Whirlpool Bath Equipment	--covered if patient is homebound and has a (standard)condition for which the whirlpool bath can be expected to provide substantial therapeutic benefit justifying its cost. Where patient is not homebound but has such a condition, payment is restricted to the cost of providing the services elsewhere; e.g., an outpatient department of a participating hospital, if that alternative is less costly. In all cases, refer claim to medical staff for a determination.
Whirlpool Pumps	--deny--(See Portable Whirlpool Pumps.) (§1861(n) of the Act)
White Cane	--deny--(See §60-3.)

60-11 HOME BLOOD GLUCOSE MONITORS

There are several different types of blood glucose monitors which use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, both with respect to the type of device and the medical condition of the patient for whom the device is prescribed.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use. However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as durable medical equipment, subject to the conditions and limitations described below.

Blood glucose monitors are meter devices which read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels. Accordingly, coverage of home blood glucose monitors is limited to patients meeting the following conditions:

- o The patient must be an insulin-treated diabetic;
- o The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a **responsible individual can be trained to use the equipment and monitor the** patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and
- o The device is designed for home rather than clinical use.

There is also a blood glucose monitoring system designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above. They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually impaired to use the equipment without assistance.

These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:

- o The patient and device meet the four conditions listed above for coverage of standard home blood glucose monitors; and
- o The patient's physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.

The additional features and equipment of these special systems justify a higher reimbursement amount than allowed for standard blood glucose monitors. Separately identify claims for such devices and establish a separate reimbursement amount for them. For those carriers using HCPCS, the procedure code and definition is: EO609--Blood Glucose Monitor--with special features (e.g., voice synthesizers, automatic timer).

60-14 INFUSION PUMPS

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE COVERED UNDER MEDICARE:

A. External Infusion Pumps.--

1. Iron Poisoning (Effective for Services Performed On or After 9/26/84).--When used in the administration of deferoxamine for the treatment of acute iron poisoning and iron overload, only external infusion pumps are covered.

2. Thromboembolic Disease (Effective for Services Performed On or After 9/26/84).--When used in the administration of heparin for the treatment of thromboembolic disease and/or pulmonary embolism, only external infusion pumps used in an institutional setting are covered.

3. Chemotherapy for Liver Cancer (Effective for Services Performed On or After 1/29/85).--The external chemotherapy infusion pump is covered when used in the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor.

4. Morphine for Intractable Cancer Pain (Effective for Services Performed On or After 4/22/85).--Morphine infusion via an external infusion pump is covered when used in the treatment of intractable pain caused by cancer (in either an inpatient or outpatient setting, including a hospice).

5. Continuous subcutaneous insulin infusion pumps (CSII) (Effective for Services Performed On or After 4/1/2000).--

An external infusion pump and related drugs/ supplies will be covered as medically necessary in the home setting in the following situation: Treatment of Type I diabetes

In order to be covered, patients must meet criterion A or B:

(A) The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen:

- (1) Glycosylated hemoglobin level (HbA1c) > 7.0%
- (2) History of recurring hypoglycemia
- (3) Wide fluctuations in blood glucose before mealtime
- (4) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
- (5) History of severe glycemic excursions

(B) The patient with Type I diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

Type I diabetes needs to be documented by a C-peptide level < 0.5

Continued coverage of the insulin pump would require that the patient has been seen and evaluated by the treating physician at least every 3 months.

The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.

Subcutaneous insulin infusion pumps will continue to be denied as not medically necessary and reasonable for all Type II diabetics including insulin-requiring Type II diabetics.

6. Other uses of external infusion pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and of the prescribed pump for the individual patient.

NOTE: Payment may also be made for drugs necessary for the effective use of an external infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

B. Implantable Infusion Pumps.--

1. Chemotherapy for Liver Cancer (Effective for Services Performed On or After 9/26/84).--The implantable infusion pump is covered for intra-arterial infusion of 5-FUdR for the treatment of liver cancer for patients with primary hepatocellular carcinoma or Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) where the patient refuses surgical excision of the tumor.

2. Anti-Spasmodic Drugs for Severe Spasticity.--An implantable infusion pump is covered when used to administer anti-spasmodic drugs intrathecally (e.g., baclofen) to treat chronic intractable spasticity in patients who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- o As indicated by at least a 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects, and

- o Prior to pump implantation, the patient must have responded favorably to a trial intrathecal dose of the anti-spasmodic drug.

3. Opioid Drugs for Treatment of Chronic Intractable Pain.--An implantable infusion pump is covered when used to administer opioid drugs (e.g., morphine) intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or nonmalignant origin in patients who have a life expectancy of at least 3 months and who have proven unresponsive to less invasive medical therapy as determined by the following criteria:

- o The patient's history must indicate that he/she would not respond adequately to non-invasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain); and

- o A preliminary trial of intraspinal opioid drug administration must be undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (including effects on the activities of daily living) and patient acceptance.

4. Coverage of Other Uses of Implanted Infusion Pumps.--Determinations may be made on coverage of other uses of implanted infusion pumps if the contractor's medical staff verifies that:

- o The drug is reasonable and necessary for the treatment of the individual patient;

o It is medically necessary that the drug be administered by an implanted infusion pump; and

o The FDA approved labelling for the pump must specify that the drug being administered and the purpose for which it is administered is an indicated use for the pump.

5. Implantation of Infusion Pump Is Contraindicated.--The implantation of an infusion pump is contraindicated in the following patients:

o Patients with a known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);

o Patients who have an infection;

o Patients whose body size is insufficient to support the weight and bulk of the device; and

o Patients with other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

NOTE: Payment may also be made for drugs necessary for the effective use of an implantable infusion pump as long as the drug being used with the pump is itself reasonable and necessary for the patient's treatment.

THE FOLLOWING INDICATIONS FOR TREATMENT USING INFUSION PUMPS ARE NOT COVERED UNDER MEDICARE:

A. External Infusion Pumps.--

1. Vancomycin (Effective for Services Beginning On or After September 1, 1996).-- Medicare coverage of vancomycin as a durable medical equipment infusion pump benefit is not covered. There is insufficient evidence to support the necessity of using an external infusion pump, instead of a disposable elastomeric pump or the gravity drip method, to administer vancomycin in a safe and appropriate manner.

B. Implantable Infusion Pump.--

1. Thromboembolic Disease (Effective for Services Performed On or After 9/26/84).-- According to the Public Health Service, there is insufficient published clinical data to support the safety and effectiveness of the heparin implantable pump. Therefore, the use of an implantable infusion pump for infusion of heparin in the treatment of recurrent thromboembolic disease is not covered.

2. Diabetes.--Implanted infusion pumps for the infusion of insulin to treat diabetes is not covered. The data do not demonstrate that the pump provides effective administration of insulin.

60-15 SAFETY ROLLER (Effective for Claims Adjudicated On or After 6/3/85)

"Safety roller" is the generic name applied to devices for patients who cannot use standard wheeled walkers. They may be appropriate, and therefore covered, for some patients who are obese, have severe neurological disorders, or restricted use of one hand, which makes it impossible to use a wheeled walker that does not have the sophisticated braking system found on safety rollers.

In order to assure that payment is not made for a safety roller when a less expensive standard wheeled walker would satisfy the patient's medical needs, carriers refer safety roller claims to their medical consultants. The medical consultant determines whether some or all of the features provided in a safety roller are necessary, and therefore covered and reimbursable. If it is determined that the patient could use a standard wheeled walker, the charge for the safety roller is reduced to the charge of a standard wheeled walker.

Some obese patients who could use a standard wheeled walker if their weight did not exceed the walker's strength and stability limits can have it reinforced and its wheel base expanded. Such modifications are routine mechanical adjustments and justify a moderate surcharge. In these cases the carrier reduces the charge for the safety roller to the charge for the standard wheeled walker plus the surcharge for modifications.

In the case of patients with medical documentation showing severe neurological disorders or restricted use of one hand which makes it impossible for them to use a wheeled walker that does not have a sophisticated braking system, a reasonable charge for the safety roller may be determined without relating it to the reasonable charge for a standard wheeled walker. (Such reasonable charge should be developed in accordance with the instructions in Medicare Carriers Manual §§5010 and 5205.)

Cross Refer: Carriers Manual §§2100ff., §60-9.

60-16. PNEUMATIC COMPRESSION DEVICES (USED FOR LYMPHEDEMA)

Lymphedema is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from an impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. It is a relatively uncommon, chronic condition which may be due to many causes, e.g., surgical removal of lymph nodes, post radiation fibrosis, scarring of lymphatic channel, onset of puberty (Milroy's Disease), and congenital anomalies. In the home setting, both the segmental and nonsegmental pneumatic compression devices are covered only for the treatment of generalized, refractory lymphedema.

Pneumatic compression devices are only covered as a treatment of last resort, i.e., other less intensive treatments must have been tried first and found inadequate. Such treatments would include leg or arm elevation and custom fabricated gradient pressure stockings or sleeves. Pneumatic compression devices may be covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include (1) the patient's diagnosis and prognosis; (2) symptoms and objective findings, including measurements which establish the severity of the condition; (3) the reason the device is required, including the treatments which have been tried and failed; and (4) the clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

In general, the nonsegmented (HCPCS code E0650) or segmented (HCPCS code E0651) compression device without manual control of pressure in each chamber is considered the least costly alternative that meets the clinical needs of the individual. Therefore, when a claim for a segmented pneumatic compression device which allows for manual control in each chamber is received, payment must be made for the least expensive medically appropriate device. If the patient medically needs a segmented device but does not need manual controls, payment must be made for HCPCS code E0651. The segmented device with manual control (HCPCS code E0652) is covered only when there are unique characteristics that prevent the individual from receiving satisfactory pneumatic treatment using a less costly device, e.g., significant sensitive skin scars or the presence of contracture or pain caused by a clinical condition that requires the more costly manual control device.

The use of pneumatic compression devices may be medically appropriate only for those patients with generalized, refractory edema from venous insufficiency

with lymphatic obstruction (i.e., recurrent cellulitis with secondary scarring of the lymphatic system) with significant ulceration of the lower extremity(ies) who have received repeated, standard treatment from a physician using such methods as a compression bandage system or its equivalent, but fail to heal after 6 months of continuous treatment. The exact nature of the medical problem must be clear from the medical evidence submitted. If, after obtaining this information, a question of medical necessity remains, the contractor's medical staff resolves the issue.

Cross Refer: §60-9.

60-17. CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) (Effective for Claims Adjudicated on and After January 12, 1987.)

CPAP is a non-invasive technique for providing low levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA). The diagnosis of OSA requires documentation of at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6-7 hours of recorded sleep. The use of CPAP is covered under Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP.

Initial claims must be supported by medical documentation (separate documentation where electronic billing is used), such as a prescription written by the patient's attending physician, that specifies:

- o a diagnosis of moderate or severe obstructive sleep apnea, and
- o surgery is a likely alternative.

The claim must also certify that the documentation supporting a diagnosis of OSA (described above) is available.

Cross Refer: §60-9.

60-18. HOSPITAL BEDS

A. General Requirements for Coverage of Hospital Beds.--A physician's prescription, and such additional documentation as the contractors' medical staffs may consider necessary, including medical records and physicians' reports, must establish the medical necessity for a hospital bed due to one of the following reasons:

- o The patient's condition requires positioning of the body; e.g., to alleviate pain, promote good body alignment, prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed; or
- o The patient's condition requires special attachments that cannot be fixed and used on an ordinary bed.

B. Physician's Prescription.--The physician's prescription, which must accompany the initial claim, and supplementing documentation when required, must establish that a hospital bed is medically necessary. If the stated reason for the need for a hospital bed is the patient's condition requires positioning, the prescription or other documentation must describe the medical

condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition, that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient's condition requires special attachments, the prescription must describe the patient's condition and specify the attachments that require a hospital bed.

C. Variable Height Feature.--In well documented cases, the contractors' medical staffs may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:

- o Severe arthritis and other injuries to lower extremities; e.g., fractured hip. The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;

- o Severe cardiac conditions. For those cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down;

- o Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair, with or without help; or

- o Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.

D. Electric Powered Hospital Bed Adjustments.--Electric powered adjustments to lower and raise head and foot may be covered when the contractor's medical staff determines that the patient's condition requires frequent change in body position and/or there may be an immediate need for a change in body position (i.e., no delay can be tolerated) and the patient can operate the controls and cause the adjustments. Exceptions may be made to this last requirement in cases of spinal cord injury and brain damaged patients.

E. Side Rails.--If the patient's condition requires bed side rails, they can be covered when an integral part of, or an accessory to, a hospital bed.

Cross refer: Carriers Manual, §5015.4

60-19. AIR-FLUIDIZED BED (Effective for services rendered on or after: 07/30/90)

An air-fluidized bed uses warm air under pressure to set small ceramic beads in motion which simulate the movement of fluid. When the patient is placed in the bed, his body weight is evenly distributed over a large surface area which creates a sensation of "floating." Medicare payment for home use of the air-fluidized bed for treatment of pressure sores can be made if such use is reasonable and necessary for the individual patient.

A decision that use of an air-fluidized bed is reasonable and necessary requires that:

- o The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore;

condition, e.g., cardiac disease, chronic obstructive pulmonary disease, quadriplegia or paraplegia, and also the severity and frequency of the symptoms of the condition, that necessitates a hospital bed for positioning.

If the stated reason for requiring a hospital bed is the patient's condition requires special attachments, the prescription must describe the patient's condition and specify the attachments that require a hospital bed.

C. Variable Height Feature.--In well documented cases, the contractors' medical staffs may determine that a variable height feature of a hospital bed, approved for coverage under subsection A above, is medically necessary and, therefore, covered, for one of the following conditions:

- o Severe arthritis and other injuries to lower extremities; e.g., fractured hip. The condition requires the variable height feature to assist the patient to ambulate by enabling the patient to place his or her feet on the floor while sitting on the edge of the bed;

- o Severe cardiac conditions. For those cardiac patients who are able to leave bed, but who must avoid the strain of "jumping" up or down;

- o Spinal cord injuries, including quadriplegic and paraplegic patients, multiple limb amputee and stroke patients. For those patients who are able to transfer from bed to a wheelchair, with or without help; or

- o Other severely debilitating diseases and conditions, if the variable height feature is required to assist the patient to ambulate.

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A decision that use of an air-fluidized bed is reasonable and necessary requires that:

- o The patient has a stage 3 (full thickness tissue loss) or stage 4 (deep tissue destruction) pressure sore;

- o The patient is bedridden or chair bound as a result of severely limited mobility;
- o In the absence of an air-fluidized bed, the patient would require institutionalization;
- o The air-fluidized bed is ordered in writing by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing. This course of treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment has been rendered.
 - o Use of wet-to-dry dressings for wound debridement, begun during the period of conservative treatment and which continue beyond 30 days, will not preclude coverage of air-fluidized bed. Should additional debridement again become necessary, while a patient is using an air-fluidized bed (after the first 30-day course of conservative treatment) that will not cause the air-fluidized bed to become non-covered. In all instances documentation verifying the continued need for the bed must be available.
 - o Conservative treatment must include:
 - Frequent repositioning of the patient with particular attention to relief of pressure over bony prominences (usually every 2 hours);
 - Use of a specialized support surface (Group II) designed to reduce pressure and shear forces on healing ulcers and to prevent new ulcer formation;
 - Necessary treatment to resolve any wound infection;
 - Optimization of nutrition status to promote wound healing;
 - Debridement by any means (including wet to dry dressings-which does not require an occlusive covering) to remove devitalized tissue from the wound bed;
 - Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings protected by an occlusive covering, while the wound heals.
 - o A trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage;
 - o A physician directs the home treatment regimen, and reevaluates and recertifies the need for the air-fluidized bed on a monthly basis; and
 - o All other alternative equipment has been considered and ruled out.

Home use of the air-fluidized bed is not covered under any of the following circumstances:

- o The patient has coexisting pulmonary disease (the lack of firm back support makes coughing ineffective and dry air inhalation thickens pulmonary secretions);

- o The patient requires treatment with wet soaks or moist wound dressings that are not protected with an impervious covering such as plastic wrap or other occlusive material; an air-fluidized bed;
- o The caregiver is unwilling or unable to provide the type of care required by the patient on an air-fluidized bed;
- o Structural support is inadequate to support the weight of the air-fluidized bed system (it generally weighs 1600 pounds or more);
- o Electrical system is insufficient for the anticipated increase in energy consumption; or
- o Other known contraindications exist.

Coverage of an air-fluidized bed is limited to the equipment itself. Payment for this covered item may only be made if the written order from the attending physician is furnished to the supplier prior to the delivery of the equipment. Payment is not included for the caregiver or for architectural adjustments such as electrical or structural improvement.
Cross refer: Carriers Manual, §5102.2.

60-20 TRANSCUTANEOUS ELECTRIC AL NERVE STIMULATORS (TENS)

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. (See §45-25 for an explanation of coverage of medically necessary supplies for the effective use of TENS and §45-19 for an explanation of coverage of TENS for acute post-operative pain.)

60-21 INTRAPULMONARY PERCUSSIVE VENTILATOR (IPV) - NOT COVERED

IPV is a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient's chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.

Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting. There are no data to support the effectiveness of the device. Therefore, IPV in the home setting is not covered.

60-22 VAGUS NERVE STIMULATION FOR TREATMENT OF SEIZURES

In the past 10 years, there have been significant advances in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, 25-50 percent of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs.

The vagus nerve is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The majority of vagal nerve fibers are visceral afferents with wide distribution. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that vagal visceral afferents have a diffuse central nervous system projection and the activation of these pathways has a widespread effect upon neuronal excitability. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, the hippocampus, the thalamus, and the cerebellum.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead and an external programming system used to change stimulation settings. Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered for patients with other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.

60-23 SPEECH GENERATING DEVICES

Effective January 1, 2001, augmentative and alternative communication devices or communicators, which are hereafter referred to as "speech generating devices" are now considered to fall within the DME benefit category established by §1861(n) of the Social Security Act. They may be covered if the contractor's medical staff determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device based on the following definitions.

Definition of Speech Generating Devices

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating are characterized by:

- o Being a dedicated speech device, used solely by the individual who has a severe speech impairment;
- o May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time;
- o May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time;
- o May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- o May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access; or
- o May be software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of §1861(n) are characterized by:

60-24 NON-IMPLANTABLE PELVIC FLOOR ELECTRICAL STIMULATOR

Non-implantable pelvic floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

The methods of pelvic floor electrical stimulation vary in location, stimulus frequency (Hz), stimulus intensity or amplitude (mA), pulse duration (duty cycle), treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings. In general, the stimulus frequency and other parameters are chosen based on the patient's clinical diagnosis.

Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

- o Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical functions.
- o Laptop computers, desktop computers, or PDAs, which may be programmed to perform the same function as a speech generating device, are non-covered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech generating devices for Medicare coverage purposes.
- o A device that is useful to someone without severe speech impairment is not considered a speech generating device for Medicare coverage purposes.

65 PROSTHETIC DEVICES

65-1 HYDROPHILIC CONTACT LENSES

Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in §1862(a)(7) of the law and are not covered when used in the treatment of nondiseased eyes with spherical ametropia, refractive astigmatism, and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.

Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval.

(See §45-7 for coverage of a hydrophilic lens as a corneal bandage.)

Cross-refer: Intermediary Manual, §§3110.3, 3110.4, 3151, and 3157; Carriers Manual, §§2130, 2320; Hospital Manual, §§228.3, 228.4, 260.1 and 260.7.

65-2 ELECTRICAL CONTINENCE AID--NOT COVERED

An electrical continence aid is a device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety. Therefore, they are not covered under Medicare since they cannot be considered to be reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by §1862(a)(1) of the law.

65-3 SCLERAL SHELL

Scleral shell (or shield) is a catchall term for different types of hard scleral contact lenses.

A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue.

In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell under §1861(s)(8) of the law.

Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate, and are continually replaced by the lacrimal gland.

When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided.

The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal

gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-refer: HCFA-Pub. 13-3, §§3110.4, 3110.5; HCFA-Pub. 14-3, §§2130, 2133; HCFA-Pub. 10, §§210.4, 211

65-4 CAROTID SINUS NERVE STIMULATOR

Implantation of the carotid sinus nerve stimulator is indicated for relief of angina pectoris in carefully selected patients who are refractory to medical therapy and who after undergoing coronary angiography study either are poor candidates for or refuse to have coronary bypass surgery. In such cases, Medicare reimbursement may be made for this device and for the related services required for its implantation.

However, the use of the carotid sinus nerve stimulator in the treatment of paroxysmal supraventricular tachycardia is considered investigational and is not in common use by the medical community. The device and related services in such cases cannot be considered as reasonable and necessary for the treatment of an illness or injury or to improve the functioning of a malformed body member as required by §1862(a)(1) of the law.

Cross-refer: HCFA-Pub. 13-3,§3110.4; HCFA-Pub. 14-3, §2130; HCFA-Pub. 10, §§210.4, 211

65-5 ELECTRONIC SPEECH AIDS

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-refer: HCFA-Pub. 13-3, §3110.4; HCFA-Pub. 14-3, §2130; HCFA-Pub. 10, §228.4

65-6 CARDIAC PACEMAKERS

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the conditions and limitations described in this section. While cardiac pacemakers have been covered under Medicare for many years, until recently there have been no specific guidelines for their implantation other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for pacemaker implantations on or after the effective dates of this instruction are subject to the guidelines of this section.

These guidelines are based on certain assumptions regarding the clinical goals of pacemaker implantation. While some uses of pacemakers represent relatively certain or unambiguous usage, many others require considerable expertise and judgment.

Consequently, the medical necessity for pacemaker implantation must be viewed in the context of the overall management of the particular patient. The appropriateness of such implants may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemakers are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which pacemaker implantation may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of pacemaker implants can be expected to change, and instructions modified as more information becomes available.

It should be noted that this instruction applies only to permanent, implanted pacemakers, and does not address the use of temporary, nonimplanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacemaker implants for patients in general. These are intended as guidelines for Medicare contractors to use in assessing the medical necessity of claims for pacemaker implantation. As with other guidelines, final coverage determinations must take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient. However, as a general rule, contractors may view the two groups of current medical concepts below as representing:

Group I: Single-Chamber Cardiac Pacemakers--A) conditions under which single-chamber pacemaker claims may be considered covered without further claims development; and B) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

Group II. Dual-Chamber Cardiac Pacemakers--A) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and B) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single-and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

GROUP I: SINGLE-CHAMBER CARDIAC PACEMAKERS--Effective for services rendered on or after March 16, 1983.

A. COVERED

Conditions under which implantation of a cardiac pacemaker is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third degree) AV heart block.
2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.
3. Second degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat).
4. Second degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.
5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
7. Sinus bradycardia which is the consequence of long-term necessary drug treatment for which there is no acceptable alternative, when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.
8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block--i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest--when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

13. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Mobitz Type II second degree AV block in association with bundle branch block.

14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

Effective for services rendered on or after **May 9, 1985**.

15. Second degree AV heart block of Type I with the QRS complexes prolonged.

B. NOT COVERED--Additional claims development may be required.

Conditions which, although used by some physicians as bases for permanent pacemaker implantation, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of indications cited above.

Contractors should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim. The object of such further development is to establish whether the particular claim actually meets the conditions in A. above. In claims where this is not the case or where such an event appears unlikely, the contractor may deny the claim.

1. Syncope of undetermined cause.
2. Sinus bradycardia without significant symptoms.
3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged R-R intervals with atrial fibrillation (without third degree AV block) or with other causes of transient ventricular pause.
5. Bradycardia during sleep.
6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block.
7. Asymptomatic second degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle.

GROUP II: DUAL-CHAMBER CARDIAC PACEMAKERS--Effective for services rendered on or after **May 9, 1985**.

A. COVERED

Conditions under which implantation of a dual-chamber cardiac pacemaker is considered acceptable or necessary in the general medical community unless **conditions #1 and #2, Group II.B., are present**):

1. Patients in whom single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.
2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.
3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with congestive heart failure despite adequate other medical measures.
4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions, as listed in Group I.A. (Single-Chamber Cardiac Pacemakers), if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. NOT COVERED

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions--e.g., chronic atrial fibrillation or flutter, or giant left atrium.
2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.
3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.
4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third degree) and/or Type II second degree AV block in association with bundle branch block.

Cross refer: HCFA Pub. 13-3, §§3101.4, 3110.4, HCFA Pub. 14-3, §2130; HCFA Pub. 10, §§210.4, 228.4.

65-7 INTRAOCULAR LENSES (IOLs)

An intraocular lens, or pseudophakos, is an artificial lens which may be implanted to replace the natural lens after cataract surgery. Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including pre-implantation ultrasound (A-scan) eye measurement of one or both eyes.

Cross-refer: HCFA Pub. 13-3, §§3110.4, 3151, and 3157; HCFA Pub.14-3, §2130; HCFA Pub. 10, §228.4

65-8 ELECTRICAL NERVE STIMULATORS

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators.--Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch. Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in §35-46, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators).--The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations.--There are two types of implantations covered by this instruction:

a. Dorsal Column (Spinal Cord) Neurostimulation.--The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.

b. Depth Brain Neurostimulation.--The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage.--No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:

a. The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;

b. With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;

c. Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);

d. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item c) must be available; and

e. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Contractors may find it helpful to work with PROs to obtain the information needed to apply these conditions to claims.

See Intermediary Manual, §3110.4 and §§35-20 and 35-27.

65-9 INCONTINENCE CONTROL DEVICES

A. Mechanical/Hydraulic Incontinence Control Devices.--Mechanical/hydraulic incontinence control devices are accepted as safe and effective in the management of urinary incontinence in patients with permanent anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device. Such a device is covered when its use is reasonable and necessary for the individual patient.

B. Collagen Implant.--A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4 week period.

In male patients, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The patient then is asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the patient leaks, the diagnosis of ISD is established.

In female patients, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H₂O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) **when the bladder has been filled with a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H₂O, the diagnosis of ISD is established.**

To use a collagen implant, physicians must have urology training in the use of a cystoscope and must complete a collagen implant training program.

Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD:

- o Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- o Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- o Male patients following trauma, including prostatectomy and/or radiation; and
- o **Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H₂O or less.**

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further

treatment of urinary incontinence by collagen implant is covered. Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

See Intermediary Manual, §3110.4.

C. Non-Implantable Pelvic Floor Electrical Stimulator.--(See §60-24.)

65-10 ENTERAL AND PARENTERAL NUTRITIONAL THERAPY COVERED AS PROSTHETIC DEVICE (Effective for items and services furnished on or after 07-11-84.)

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision, which requires that the patient must have a permanently inoperative internal body organ or function thereof. (See Intermediary Manual, §3110.4.) Therefore, enteral and parenteral nutritional therapy are not covered under Part B in situations involving temporary impairments. Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Intermediary Manual, §3110.4.

65-10.1 Parenteral Nutrition Therapy.--Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition

therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than 3 months by the carrier's medical consultant or specially trained staff, relying on such medical and other documentation as the carrier may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive pre-mixed solutions only under the latter circumstances.

65-10.2 Enteral Nutrition Therapy.--Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the contractor's medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time.

If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

65-10.3 Nutritional Supplementation.--Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

65-11 BLADDER STIMULATORS (PACEMAKERS)--NOT COVERED

There are a number of devices available to induce emptying of the urinary bladder by using electrical current which forces the muscles of the bladder to contract. These devices (commonly known as bladder stimulators or pacemakers) are characterized by the implantation of electrodes in the wall of the bladder, the rectal cones, or the spinal cord. While these treatments may effectively empty the bladder, the issue of safety involving the initiation of infection, erosion, placement, and material selection has not been resolved. Further, some facilities previously using electronic emptying have stopped using this method due to the pain experienced by the patient.

The use of spinal cord electrical stimulators, rectal electrical stimulators, and bladder wall stimulators is not considered reasonable and necessary. Therefore, no program payment may be made for these devices or for their implantat

65-13 PHRENIC NERVE STIMULATOR

The implantation of a phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency.

The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs). The device has been used successfully to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord and chronic pulmonary disease with ventilatory insufficiency. The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma.

However, an implanted phrenic nerve stimulator can be effective only if the patient has an intact phrenic nerve and diaphragm. Moreover, nerve injury may occur during the surgical procedure and if sufficient injury is incurred, the device will not prove useful to the patient. Consequently, it is possible for such a device to be indicated for a patient but, due to injury sustained during implant, fail to assist the patient, resulting in a return to the use of mechanical ventilation.

65-14 COCHLEAR IMPLANTATION

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, **analyze and code** sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide an awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

Medicare coverage is provided only for those patients who meet all of the following selection guidelines.

A. General.--

- o Diagnosis of bilateral severe-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- o Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- o Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- o No contraindications to surgery; and
- o The device must be used in accordance with the FDA-approved labeling.

B. Adults.--Cochlear implants may be covered for adults (over age 18) for prelinguistically, perilinguistically, and postlinguistically deafened adults. Postlinguistically deafened adults must demonstrate test scores of 30 percent or less on sentence recognition scores from tape recorded tests in the patient's best listening condition.

C. Children.--Cochlear implants may be covered for prelinguistically and postlinguistically deafened children aged 2 through 17. Bilateral profound sensorineural deafness must be demonstrated by the inability to improve on age appropriate closed-set word identification tasks with amplification.

65-15 ARTIFICIAL HEARTS AND RELATED DEVICES

A ventricular assist device (VAD) is used to assist a damaged or weakened heart in pumping blood. VADs are used as either a bridge to a heart transplant or for support of blood circulation postcardiotomy, which is the period following open heart surgery. VADs used for support of blood circulation postcardiotomy are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA approved labeling instructions. Since there is no authoritative evidence substantiating the safety and effectiveness of a VAD used as a replacement for the human heart, Medicare does not cover this device when used as an artificial heart.

All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge to transplant:

1. The VAD must be used in accordance with the FDA approved labeling instructions. This means that the VAD is used as a temporary mechanical circulatory support for approved transplant candidates as a bridge to cardiac transplantation;
2. The patient is approved and listed as a candidate for heart transplantation by a Medicare approved heart transplant center; and,
3. The VAD is implanted in a Medicare approved heart transplant center on a patient who is listed by that center. If the patient is listed by another Medicare approved transplant center, the implanting center must receive written permission from the center under which the patient is listed.

Centers implanting VADs should make every reasonable effort to transplant patients on such devices as soon as medically reasonable. Ideally, the centers should determine patient-specific timetables for transplantation and should not maintain such patients on VADs if suitable hearts become available.

65-16 TRACHEOSTOMY SPEAKING VALVE

A trachea tube has been determined to satisfy the definition of a prosthetic device, and the tracheostomy speaking valve is an add on to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words, it makes the system a better prosthesis.

As such, a tracheostomy speaking valve is covered as an element of the trachea tube which makes the tube more effective.

65-17 URINARY DRAINAGE BAGS

Urinary collection and retention system are covered as prosthetic devices that replace bladder function in the case of permanent urinary incontinence. Urinary drainage bags that can be used either as bedside or leg drainage bags may be either multi-use or single use systems. Both the multi-use and the single use bags have a system that prevents urine backflow. However, the single use system is non-drainable. There is insufficient evidence to support the medical necessity of a single use system bag rather than the multi-use bag. Therefore, a single use drainage system is subject to the same coverage parameters as the multi-use drainage bags.